K001891

JUL 12 2000

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SUMMARY OF SAFETY AND EFFECTIVENESS
MICROSAMPLE COAGULATION ANALYZER™, MODEL MCA 310 - C

This **Special** 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications, March 20, 1998, for Modified Devices.

Effectiveness Summary:

Correlation of Microsample Coagulation Analyzer, Model MCA 310 - C, with the Platelet Aggregation Profiler, Model PAP-4C.

Control and Donor Plasma testing at Bio/Data Corporation, Horsham, PA and Sheffield Haemophilia and Thrombosis Center, Royal Hallamshire Hospital, Shffield, UK:

Mathematically, as calculated by formulas supplied in Microsoft® Excel™ (v 5.0), the following Slopes, Intercepts and Correlation Coefficients (r) were determined for each of the test types:

	AT III	Plasminogen	Protein C	Heparin	Overall
r	0.9568	0.9368	0.8883	0.9507	0.9212
Slope	0.9447	1.0379	1.3084	1.0047	1.1339
Intercept	-0.239	-6.931	-14.69	-4.048	-9.48

The correlation between the instrument data sets was analyzed.

Analysis showed the Correlation Coefficients (r) was greater than 0.88. Laboratory standards accept correlations of 0.85 as being satisfactory. The determined Slopes and Intercepts were within accepted laboratory standards.

Conclusion: The Microsample Coagulation Analyzer, Model MCA 310 - C is substantially equivalent to the PAP-4C when performing chromogenic assays.

Comparison of Model MCA 310 -C dilution system and resultant Chromogenic Assay test samples prepared manually and run on an PAP-4C.

Dilution comparison, testing at Bio/Data Corporation, Horsham, PA:

Chromogenic Assays for Antithrombin III, Plasminogen, Protein C and Heparin (Xa) were completed on both the MCA 310 - C (using automated diluting) and PAP-4C (using manual diluting). The results from these assays were correlated as to Percent Activity (%) or International Units (IU). This testing generated the following correlation data:

	AT III (%)	Plasminogen (%)	Protein C (%)	Heparin (IU)
r	0.9553	0.9382	0.9143	0.9722
Slope	0.9700	0.8400	0.6100	0.8100
Intercept	0.06	0.16	0.24	0.07

The Correlation Coefficient was greater than 0.91 for either Chromogenic Assay System. Laboratory standards accepts correlations of 0.9 as satisfactory.

Conclusion: The Microsample Coagulation Analyzer, Model MCA 310 - C (chromogenic module) is substantially equivalent to the PAP-4C when performing chromogenic assays.

Effectiveness of the sampling system.

During operational testing of the MCA 310 observations were made relating to the effectiveness of the sampling system. The analysis of these observations, as reported for the MCA 310, Section 510(k) (March 1995), generated the following data related to average Standard Deviations (SD) and Coefficients of Variation (CV):

	Average PT SD	Average FIB SD	Average APTT SD
MCA 310	0.11	5.65	0.72
Manual Sampling	0.12	4.28	0.41

	Average PT CV	Average FIB CV	Average APTT CV
MCA 310	0.73%	2.11%	1.53%
Manual Sampling	0.72%	1.65%	1.07%

Conclusions: The sampling system of the Microsample Coagulation Analyzer, Model MCA 310 is substantially equivalent to manual sampling commonly used in the laboratory.

Safety Summary:

Design and Engineering:

The MCA 310 - C requires no special handling. It operates in the normal laboratory environment. The product does not support or sustain human life nor does it present a reasonable risk of illness or injury. The product has been found to be safe in general laboratory use when the instructions contained in the Operation Manual are followed.

Rodney W. Scarpelli 6/19/00

Rodney W. Scarpelli

Regulatory Affairs
Quality Assurance Manager
Bio/Data Corporation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 12 2000

Mr. Rodney W. Scarpelli
Quality Assurance Manager
Bio/Data Corporation
155 Gibraltar Road
P.O. Box 347
Horsham, Pennsylvania 19044-0347

Re: K001891
Trade Name: Microsample Coagulation Analyzer
Regulatory Class: II
Product Code: GKP
Dated: June 20, 2000
Received: June 21, 2000

Dear Mr. Scarpelli:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K001891

Device Name: Microsample Coagulation Analyzer, Model MCA 310 C

Indications For Use:

The Microsample Coagulation Analyzer, Model MCA 310 - C, is intended for routine use in the clinical laboratory as a coagulation analyzer. The fibrin end-point detection method is used for diagnostic screening and laboratory monitoring of oral anticoagulants. The chromogenic detection method is used for the performance of specialty diagnostic and confirmatory coagulation tests.

Chromogenic tests currently avaialble on the MCA 310 - C are Antitrommbin III, Heparin (anti Xa), Plasminogen and Protein C.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joan E Markin

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001891

Rodney W. Hampton 7-10-00

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)